GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:2612
ANSWERED ON:17.03.2017
Adverse Drug Reaction
Siddeshwara Shri Gowdar Mallikarjunappa

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) the number of Adverse Drug Reaction monitoring centres working at present in the country;

(b) whether the cases of adverse drug reaction have come to the notice of the Government during the last three years and the current year and if so, the details thereof and the action taken by the Government thereon;

(c) whether the Government has formulated any scheme to withdraw the drugs from the market, impose regulatory ban on them due to the problem of drug reaction; and

(d) if so, the details thereof during the said period and if not, the reasons therefor?

Answer

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND
FAMILY WELFARE
(SHRI FAGGAN SINGH KULASTE)
(a): At present, there are 210 Adverse Drug Reaction Monitoring centres (AMCs) in the country under the Pharmacovigilance Programme of India (PvPI).
(b): No drug is 100% safe and all drugs are allowed to be marketed based on risk-benefit assessment. The Government of India has started the PvPI with a view to gather information/data about Adverse Drug Reactions (ADR). Such data is used to develop effective, safe medications and doses and provide specific information to the end users, doctors, regulators and also industry. During 2014 to 2016, as many as 1,65,505 ADRs have been reported under the PvPI.
(c)&(d): The Central Government prohibits manufacture, sale and distribution of drugs that are not found to be safe or rational. The Government of India has so far prohibited/restricted/suspended 439 drugs, including 344 Fixed Dose Combination (FDC) drugs for manufacture, sale and distribution in the country. However, the High Court of Delhi has quashed the notifications prohibiting the 344 FDCs vide its judgment dated 01.12.2016. No drugs have been banned based on ADRs received under PvPI.
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